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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,319	08/31/2001	Miriam Lane	21819.00169	2718

7590

11/07/2002

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EXAMINER

RUDDY, DAVID M

#8

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 11/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/945,319

Applicant(s)

LANE ET AL.

Examiner

David M Ruddy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-26 is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 10, 12, 13, 15, 16, 20 and 21 is/are rejected.
- 7) ☒ Claim(s) 8, 11, 14 and 17-19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7. 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the limitation "a second direction of rotation" presupposes the existence of a first direction of rotation. Claim 18 (not any of its base claims) does not include a recitation of a first direction of rotation. Accordingly, there is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim 1-7, 9, 10, 12-13, 15, 16, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Lafontaine (patent #6,290,696). Lafontaine discloses (as seen in figure 2) a catheter comprising an elongate catheter body (12), a cooling chamber (42), and an expandable member (14) which envelops the cooling chamber. The expandable

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member is disposed around the chamber such that there is an interstitial space therebetween. As explained in column 4, lines 15-25, there is disclosed a fluid source of evacuation. Also disclosed in the same passage, is the description of the chamber as an expandable membrane inflatable from a first to a second state. As seen in figures 1 and 2, tube 30 is connected to a source of coolant (20). In regard to the limitations of claim 7, there is disclosed a source of fluid evacuation with reference to item 44 and the passages of column 4, line 15-25. Noting the change in diameter of the balloon 14, the limitations of claim 10 are met in that the change in diameter meets the broad limitation of "non-uniform".

In regard to the limitations of claims 12-13, it is noted that the limitations include recitation regarding the method of formation of the device. Applicant is reminded with reference to section 2113 of the MPEP that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

In regard to the limitations of claim 15, the recitation of "small particles" appears to be broad enough to be met by the fluid injected into the interstitial space.

Lafontaine discloses a temperature sensor as seen by items (22 and 24).

Allowable Subject Matter

Claims 22-26 are allowed. The prior art does not teach the combination of a catheter system including a cooling chamber, an expandable member and primary and secondary return lumens as set forth in claim 22.

Claims 8, 11, 14, 17, 18, and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach a secondary coolant return lumen in combination with the limitations of the claims preceding claim 8. The prior art does not teach the use of a patterned inner or outer surface in order to enhance the flow capacity of fluid flow in combination with the limitations of the claims preceding claim 11. The prior art does not teach the use of a plurality of raised surfaces in either the inner or outer surface of the device in combination with the limitations of the claims preceding claim 14. The prior art does not teach the added feature of a flexible elongate element wound in a direction of rotation around the cooling chamber in combination with the limitations of the claims preceding claims 17-18.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The references of Aliberto et al. and Joye et al. both disclose cooling chamber within balloon designs similar to that of the present application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M Ruddy whose telephone number is (703) 308-3595. The examiner can normally be reached on Mon-Fri 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3376 for regular communications and (703) 746-3376 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

A handwritten signature in black ink, appearing to read 'Linda C. M. Dvorak', is written over a large, faint circular stamp.

LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700

DR
November 1, 2002